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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,930	03/17/2005	Shou Takashima	P25687	2173

7055 7590 06/15/2006

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EXAMINER

RAGHU, GANAPATHIRAM

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 06/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/501,930	Applicant(s) TAKASHIMA ET AL.	
	Examiner Ganapathirama Raghu	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 May 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 16-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 March 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>05/06/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-30 are pending in this application for examination. Claims 1-15 are now under consideration. Claims 16-30 are withdrawn as they are drawn to non-elected invention.

Election/Restrictions

Applicant's election of Group I, claims 1-15, polypeptide sequence of SEQ ID NO: 1 and polynucleotide sequence of SEQ ID NO: 2 with traverse for prosecution in the reply filed on May 24, 2006 is acknowledged. The traversal is on the grounds that the restriction is improper, unity of invention exists between the restricted groups and all the claims are closely related and examination of all the claims will not pose a serious search burden.

Applicants arguments of "No lack of unity was found by the Examiner and restriction be withdrawn" is answered as follows.

1. The traversal is on the grounds that the Office has not provided sufficient reasons for restriction of different groups and therefore restriction between groups be withdrawn and have requested for examination of all the claims. Applicant's arguments have been fully considered but are not deemed persuasive to withdraw the restriction requirement previously applied. If the examiner finds that the national stage application lacks unity of invention under 37 CFR 1.475, the examiner may in an Office Action require the applicant in the response to that action to elect an invention to which the claims shall be restricted. Such requirement may be made before any action at the discretion of the examiner.

2. Applicant's argument of all the claims are linked by special technical features and have unity of invention is not persuasive because Kawai et al., (Nature 2001, Vol. 409: 685- 690, also

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see supplementary Table 4)) teach the isolation of a polynucleotide encoding a polypeptide that is functionally annotated as sialyltransferase with 100% homology to the polynucleotide of SEQ ID NO: 2 and the encoded polypeptide of SEQ ID NO: 1 of the instant application. Therefore the technical features linking the inventions of Groups I-II does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art. Further evidence that the claims lack special technical feature is found under U.S.C. 102 (a) below.

Therefore contrary to applicant's argument, the requirement for restriction is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 05 May 2005 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the Examiner is considering the information disclosure statement.

Drawings

Drawings are accepted for examination purposes only.

Specification: Sequence Compliance

The disclosure is objected to because of the following informalities:

Applicants are required to comply with the sequence rules by inserting the sequence identification numbers of all sequences within the claims and /or specification. It is particularly noted that Figures: 1A-B, 2A-B, 7A, 8A and 9A-B are sequences, but applicants fail to provide

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the SEQ ID NO: to these sequences in the figures (Drawings section) or in the figure description of the specification. See particularly 37 CFR 1.821(d).

Claim Rejections 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-4 are rejected under 35 U.S.C. 101 because the claim could read on a non-statutory subject matter. The claims are drawn to a "O-glycan α 2,8-sialyltransferase" or "A gene", which could read on product of nature. Claims directed to such matter are considered non-statutory. Examiner suggests amending the claim to recite "An isolated O-glycan α 2,8-sialyltransferase" or "An isolated gene" to show the hand of man and in order to overcome the rejection.

Claims 7 and 14 are rejected under 35 U.S.C. 101 because the claim could read on a non-statutory subject matter. The claim is drawn to 'A transformant...', which could be a human being. Claims directed to such matter are considered non-statutory. Examiner suggests amending the claim to recite 'An isolated transformed host cell' to show the hand of man and in order to overcome the rejection.

Claim 9 is rejected under 35 U.S.C. 101 because the claim could read on a non-statutory subject matter. The claim is drawn to 'A protein', which could read on product of nature. Claims

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directed to such matter are considered non-statutory. Examiner suggests amending the claim to recite 'An isolated protein' to show the hand of man and in order to overcome the rejection.

Claim 10 is rejected under 35 U.S.C. 101 because the claim could read on a non-statutory subject matter. The claim is drawn to 'An extracellular secretory protein', which could read on product of nature. Claims directed to such matter are considered non-statutory. Examiner suggests amending the claim to recite 'An isolated extracellular secretory protein' to show the hand of man and in order to overcome the rejection.

Claim 11 is rejected under 35 U.S.C. 101 because the claim could read on a non-statutory subject matter. The claims are drawn to 'A gene', which could read on product of nature. Claims directed to such matter are considered non-statutory. Examiner suggests amending the claim to recite 'An isolated gene' to show the hand of man and in order to overcome the rejection.

Claim Rejections: 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 2 recites the phrase "...an amino acid sequence..." (lines 3 and 4), as the metes and bounds are not clear to the examiner. It is not clear whether the claims encompass the full-length sequence of SEQ ID NO: 1 or any portion or fragments of SEQ ID NO: 1. In order for the

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full-length of the polypeptides to be encompassed in said sequences, examiner suggests amending the claims to read as "...the amino acid sequence...". Clarification and correction is required.

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 4 recites the phrase "...a nucleotide sequence shown in SEQ ID NO: 2...", as the metes and bounds are not clear to the Examiner. It is not clear if this phrase encompass only the full-length sequence of SEQ ID NO: 2 or any portion or fragments of SEQ ID NO: 2. In order for the full-length of the polynucleotide to be encompassed in said sequences, examiner suggests amending the claims to read as "...the nucleotide sequence". Clarification and correction is required.

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 4 recites the phrase "...corresponding to..." (lines 3 and 6), as the metes and bounds are not clear to the examiner. It is not clear whether the claims encompass the full-length sequence of SEQ ID NO: 2 comprising the nucleotides 77-1270 or any portion, fragments of SEQ ID NO: 2. In order for the full-length of the polynucleotide to be encompassed in said sequences, examiner suggests amending the claims to read as "...the nucleotide sequence". Clarification and correction is required.

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Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 9 recites the phrase "...corresponding to..." (lines line 3 and 6), as the metes and bounds are not clear to the examiner. It is not clear whether the claims encompass the full-length sequence of SEQ ID NO: 1 comprising the amino acid residues of 26-398 or any portion or fragments of SEQ ID NO: 1. In order for the full-length of the polypeptide to be encompassed in said sequences, examiner suggests amending the claims to read as "...the polypeptide sequence of SEQ ID NO: 1 comprising the amino acid residues of 26-398". Clarification and correction is required.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-15, are directed to an isolated O-glycan α 2,8-sialyltransferase having an amino acid sequence of SEQ ID NO: 1 or an amino acid sequence comprising a deletion, substitution, and/or addition of one or several amino acid residues to the amino acid sequence of SEQ ID NO: 1 between positions 26-398 and having O-glycan α 2,8-sialyltransferase activity, wherein said polypeptide is encoded by a polynucleotide sequence comprising the nucleotides 77-1270 of

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SEQ ID NO: 2 or a nucleotide sequence comprising a deletion, substitution, and/or addition of one or several nucleotides between the nucleotides 77-1270 of SEQ ID NO: 2 and encoding a polypeptide with O-glycan α 2,8-sialyltransferase activity, expression vectors comprising said polynucleotides and to the method of making said polypeptides. Claims 1-6, 8-13 and 15 are rejected under this section 35 U.S.C. 112, because the claims are directed to a genus polypeptides and encoding polynucleotides with no support in the specification for the structural details associated with the function i.e., O-glycan α 2,8-sialyltransferase activity, expression vectors comprising said polynucleotides and method of making said polypeptides. The specification discloses the isolation of a polypeptide with SEQ ID NO: 1 or an amino acid sequence comprising the amino residues of 26-398 of SEQ ID NO: 1 encoded by a polynucleotide of SEQ ID NO: 2 or comprising the nucleotide residues 77-1270 of SEQ ID NO: 2 and having O-glycan α 2,8-sialyltransferase activity, an expression vector comprising said polynucleotide and method of making said polypeptide. No description of identifying characteristics of all of the sequences of an isolated O-glycan α 2,8-sialyltransferase having an amino acid sequence comprising a deletion, substitution, and/or addition of one or several amino acid residues to the amino acid sequence of SEQ ID NO: 1 between positions 26-398 and having O-glycan α 2,8-sialyltransferase activity, wherein said polypeptide is encoded by a nucleotide sequence comprising a deletion, substitution, and/or addition of one or several nucleotides between the nucleotides 77-1270 of SEQ ID NO: 2 and encoding a polypeptide with O-glycan α 2,8-sialyltransferase activity, expression vectors comprising said polynucleotides and method of making said polypeptides, has been provided by the applicants, which would indicate that they had possession of the claimed genus of the polypeptides and encoding polynucleotides.

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Therefore, one skilled in the art cannot reasonably conclude that applicant had possession of the claimed invention at the time the instant application was filed. Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 1-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated of a polypeptide with SEQ ID NO: 1 or an amino acid sequence comprising the amino residues of 26-398 of SEQ ID NO: 1, encoded by a polynucleotide of SEQ ID NO: 2 or comprising the nucleotide residues 77-1270 of SEQ ID NO: 2 and having O-glycan α 2,8-sialyltransferase activity, expression vector comprising said polynucleotide and method of making said polypeptide, does not reasonably provide enablement for any isolated O-glycan α 2,8-sialyltransferase having an amino acid sequence of SEQ ID NO: 1 or an amino acid sequence comprising a deletion, substitution, and/or addition of one or several amino acid residues to the amino acid sequence of SEQ ID NO: 1 between positions 26-398 and having O-glycan α 2,8-sialyltransferase activity, wherein said polypeptide is encoded by a polynucleotide sequence comprising the nucleotides 77-1270 of SEQ ID NO: 2 or a nucleotide sequence comprising a deletion, substitution, and/or addition of one or several nucleotides between the nucleotides 77-1270 of SEQ ID NO: 2 and encoding a polypeptide with O-glycan α 2,8-sialyltransferase activity, expression vectors comprising said polynucleotides and method of making said polypeptides. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and or use the invention commensurate in scope with the claims.

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Factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands* (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)) as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claim(s).

Claims 1-15 are so broad as to encompass for any isolated O-glycan α 2,8-sialyltransferase having an amino acid sequence of SEQ ID NO: 1 or an amino acid sequence comprising a deletion, substitution, and/or addition of one or several amino acid residues to the amino acid sequence of SEQ ID NO: 1 between positions 26-398 and having O-glycan α 2,8-sialyltransferase activity, wherein said polypeptide is encoded by a polynucleotide sequence comprising the nucleotides 77-1270 of SEQ ID NO: 2 or a nucleotide sequence comprising a deletion, substitution, and/or addition of one or several nucleotides between the nucleotides 77-1270 of SEQ ID NO: 2 and encoding a polypeptide with O-glycan α 2,8-sialyltransferase activity. The scope of the claims are not commensurate with the enablement provided by the disclosure with regard to the extremely large number of polypeptides and encoding polynucleotides broadly encompassed by the claims. Since the amino acid sequence of a protein encoded by a polynucleotide determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires knowledge and guidance with regard to which amino acids in the protein's sequence and the respective codons in its polynucleotide, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in

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which the encoded proteins' structure relates to its function. However, in this case the disclosure is limited to an isolated polypeptide with SEQ ID NO: 1 and having the O-glycan α 2,8-sialyltransferase activity encoded by a polynucleotide of SEQ ID NO: 2, but provides no guidance with regard to the making of variants and mutants or with regard to other uses. In view of the great breadth of the claims, amount of experimentation required to make the claimed polypeptides and encoding polynucleotides, the lack of guidance, working examples, and unpredictability of the art in predicting function from a polypeptide primary structure (e.g., see Ngo et al. in *The Protein Folding Problem and Tertiary Structure Prediction*, 1994, Merz et al. (ed.), Birkhauser, Boston, MA, pp. 433 and 492-495), the claimed invention would require undue experimentation. As such, the specification fails to teach one of ordinary skill how to use the full scope of the polypeptides encompassed by this claim.

While enzyme isolation techniques, recombinant and mutagenesis techniques are known, and it is not routine in the art to screen for multiple substitutions or multiple modifications as encompassed by the instant claim, the specific amino acid positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions or deletions.

The specification does not support the broad scope of the claims which encompass all modifications of polypeptide with SEQ ID NO: 1 or an amino acid sequence comprising the amino residues of 26-398 of SEQ ID NO: 1 encoded by a polynucleotide of SEQ ID NO: 2 or

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comprising the nucleotide residues 77-1270 of SEQ ID NO: 2 and having O-glycan α 2,8-sialyltransferase activity, because the specification does not establish: (A) regions of the protein/polynucleotide structure which may be modified without affecting the activity of encoded O-glycan α 2,8-sialyltransferase activity; (B) the general tolerance of the polypeptide and the polynucleotide encoding O-glycan α 2,8-sialyltransferase to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any amino acid residue or the respective codon in the polynucleotide with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including polypeptides and encoding polynucleotides with an enormous number of modifications. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of polypeptides and encoding polynucleotides of O-glycan α 2,8-sialyltransferase having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claim 7 and 14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, because, while claims 7 and 14 are being enabling for an isolated host cell transformed with the synthetic nucleic acid, does not reasonably provide

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enablement for transgenic multi-cellular organisms or host cells within a multi-cellular organism that have been transformed with the synthetic nucleic acid. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Claim 7 and 14 are so broad as to encompass transgenic multi-cellular organisms and host cells transformed with specific nucleic acids, including cells in *in vitro* culture as well as within any multi-cellular organism. The scope of the claims are not commensurate with the enablement provided by the disclosure with regard to extremely large number of transformed organisms broadly encompassed by the claims. While methods for transforming cells *in vitro* are well known in the art, methods for successfully transforming cells within complex multi-cellular organisms are not routine and are highly unpredictable. Furthermore, methods for producing a successfully transformed cell within the multi-cellular organism are unlikely to be applicable to transformation of other types of multi-cellular organism as multi-cellular organisms vary widely. However, in this case the disclosure is limited to only host cells *in vitro*. Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including the use of host cells within a multi-cellular organism for the production of polypeptide. The scope of claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA)). Without sufficient guidance, expression of genes in a particular host cell and having the desired biological characteristics is unpredictable, the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and

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undue. See *In re Wands* 858 F. 2d 731, 8 USPQ 2nd 1400 (Fed. Cir., 1988). It is suggested that the applicants limit the claims to “An isolated host cell ...”.

Claim Rejections 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Kawai et al., (Nature 2001, Vol. 409: 685-690). Claims 1-4 and 9-11, are directed to an isolated O-glycan α 2,8-sialyltransferase having an amino acid sequence of SEQ ID NO: 1 or an amino acid sequence comprising a deletion, substitution, and/or addition of one or several amino acid residues to the amino acid sequence of SEQ ID NO: 1 between positions 26-398 and having O-glycan α 2,8-sialyltransferase activity, wherein said polypeptide is encoded by a polynucleotide sequence comprising the nucleotides 77-1270 of SEQ ID NO: 1 or a nucleotide sequence comprising a deletion, substitution, and/or addition of one or several nucleotides between the nucleotides 77-1270 of SEQ ID NO: 1 and encoding a polypeptide with O-glycan α 2,8-sialyltransferase activity. Claims 5-8 and 12-15 are directed to a recombinant expression vector comprising the gene encoding the polypeptide of SEQ ID NO: 1, host cell and the method of making said polypeptide. Kawai et al., teach the isolation of a polynucleotide (see supplementary Table 4, section C. InterPro Motifs of RIKEN clones, InterPro ID NO: IPR001675, annotated as

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sialyltransferase) from mouse that has 100% homology to SEQ ID NO: 2 of the instant application (see sequence alignment provided) and predicted to encode a polypeptide with sialyltransferase activity having 100% homology to the polypeptide of SEQ ID NO: 1 of the instant application (see sequence alignment provided). The reference is silent on the substrate specificity of the annotated polypeptide i.e., O-glycan $\alpha 2,8$ -sialyltransferase having substrate specificity wherein substrates are glycoconjugates having Sia $\alpha 2,3(6)$ Gal structure, however examiner takes the position, that by virtue of 100% homology to SEQ ID NO: 1 of the instant application, the polynucleotide isolated by Kawai et al., and the encoded polypeptide inherently possess the O-glycan $\alpha 2,8$ -sialyltransferase having substrate specificity wherein substrates are glycoconjugates having Sia $\alpha 2,3(6)$ Gal structure. Furthermore, the reference also teaches the recombinant expression constructs and host cells (Methods section, page 688) and therefore, Kawai et al., anticipate claims 1-15 as written.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-15 are rejected under 35 U.S.C. 102(a) as being anticipated by Takashima et al., (JBC., 2002, Vol. 277 (27): 24030-24038, on line publication April 29, 2002). Claims 1-4 and 9-11, are directed to an isolated O-glycan $\alpha 2,8$ -sialyltransferase having an amino acid sequence of SEQ ID NO: 1 or an amino acid sequence comprising a deletion, substitution, and/or addition of one or several amino acid residues to the amino acid sequence of SEQ ID NO: 1 between positions 26-398 and having O-glycan $\alpha 2,8$ -sialyltransferase activity, wherein said polypeptide is encoded by a polynucleotide sequence comprising the nucleotides 77-1270 of SEQ ID NO: 1

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or a nucleotide sequence comprising a deletion, substitution, and/or addition of one or several nucleotides between the nucleotides 77-1270 of SEQ ID NO: 1 and encoding a polypeptide with O-glycan α 2,8-sialyltransferase activity. Claims 5-8 and 12-15 are directed to a recombinant expression vector comprising the gene encoding the polypeptide of SEQ ID NO: 1, host cell and the method of making said polypeptide. Takashima et al., teach the isolation of a polypeptide and encoding polynucleotide from mouse that has 100% homology to SEQ ID NO: 2 and SEQ ID NO: 1 respectively of the instant application (see sequence alignment provided) and exhibited O-glycan α 2,8-sialyltransferase activity that sialylates O-glycans having substrate specificity wherein substrates are glycoconjugates having Sia α 2,3(6) Gal structure. Furthermore, the reference also teaches the recombinant expression constructs, host cells and method of making the polypeptides (Experimental Procedures, page 688) and therefore, Takashima et al., anticipate claims 1-15 as written. As the English translation of the foreign priority documents are not provided with the filing of the PCT application, the filing date of PCT/JP03/00883 filed on 01/30/2003 is the priority date granted for this application.

The teachings of the following references are made of record. However, these references are not used in any prior art rejections.

Carninci et al., (Methods in Enzymology 1999, Vol. 303: 19-44) teach the isolation of a cDNA and the encoding polypeptide that have 100% sequence homology to SEQ ID NO: 2 and SEQ ID NO: 1 respectively of the instant application (see sequence alignments provided). However, in said reference no biological activity is assigned to the predicted polypeptide.

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Shibata et al., (Genome Research 2000, Vol. 10: 1757-1771) teach the isolation of a cDNA and the encoding polypeptide that have 100% sequence homology to SEQ ID NO: 2 and SEQ ID NO: 1 respectively of the instant application (see sequence alignments provided). However, in said reference no biological activity is assigned to the predicted polypeptide.

Conclusion

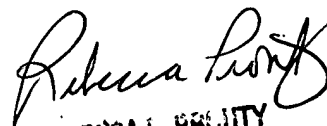
None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathirama Raghu whose telephone number is 571-272-4533. The examiner can normally be reached on 8 am - 4.30 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and for After Final communications. Any inquiry of a general nature or relating to the status of the application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ganapathirama Raghu, Ph.D.
Patent Examiner
Art Unit 1652

June 02, 2006.


REBECCA E. PRIDDY
PRIMARY EXAMINER
GROUP 1800
612